



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1400]

Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #266 entitled "Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs." The guidance describes FDA's current thinking with respect to assisting sponsors in incorporating real-world data and real-world evidence (including ongoing surveillance activities, observational studies, and registry data) into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-1400 for "Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine (HFV-131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0578, susan.storey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, the Agency has taken steps to leverage modern, rigorous analyses of real-world data to inform our work. The COVID-19 pandemic has brought an urgency to these efforts and the Agency has worked quickly to advance collaborations with public and private partners to collect and analyze a variety of real-world data sources. We recognize that real-world data sources have the potential to provide a wealth of rapid, actionable information to support and advance regulatory decision making for both human and animal drugs.

In the *Federal Register* of July 15, 2020 (85 FR 42880), FDA published the notice of availability for a draft guidance entitled "Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs," giving interested persons until October 13, 2020, to comment on the draft guidance. This guidance describes how the Center for Veterinary Medicine (CVM) intends to evaluate real-world data (RWD) and real-world evidence (RWE) in submissions to CVM to demonstrate substantial evidence of effectiveness for new animal drug applications or a reasonable expectation of effectiveness for applications for conditional approval of a new animal drug. It also provides information about how sponsors may obtain feedback from CVM on technical issues related to the use of RWD and RWE before the submission of an application.

FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to this final guidance to improve clarity. For example, we added language to provide context to the use of RWD and RWE from retrospective studies in addition to RWD and RWE from prospective studies. We also revised the language of the guidance to clarify that the term "animals" can refer to an individual animal or a flock, tank, or group depending on the context in which RWD and RWE is collected. The guidance announced in this notice finalizes the draft guidance dated July 2020.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Use of

Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in FDA's guidance entitled "Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs" have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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